UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PROCTER & GAMBLE COMPANY, Plaintiff, - against - PLAYTEX PRODUCTS, INC., Defendant.	1:08-CV-01532 (WHP) (THK) DECLARATION OF KEITH EDGETT IN SUPPORT OF PLAYTEX PRODUCTS, INC.'S OPPOSITION TO P&G'S MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION FOR SUMMARY JUDGMENT Electronically Filed

I, Keith Edgett, hereby declare:

1. I am the Vice President of Feminine Care R&D and Absorbent Materials Sciences, Playtex Division, Energizer Personal Care. I have held this position since January 2, 2006.

2. As Vice President of Feminine Care R&D and Absorbent Materials Sciences I oversaw the product development of the improved version of Gentle Glide that is currently on the market ("New Gentle Glide"). I submit this affidavit in support of Playtex Products, Inc. ("Playtex")'s opposition to The Procter & Gamble Company ("P&G")'s motion for summary judgment and cross motion for summary judgment in the above captioned matter.

3. In 2006, Playtex initiated a project to design and launch an improved version of its Gentle Glide plastic applicator tampon. Playtex invested $3.99 Million in the project.

4. As part of the project referenced in paragraph 3, Playtex made changes to, *inter alia*, the pledget of the Gentle Glide tampon. These changes resulted in the improved performance of New Gentle Glide in terms of [redacted] REDACTED [redacted] and fluid displacement as compared to the version of Gentle Glide that was previously on the market ("Old Gentle Glide").

5. The pledget is the absorbent portion of a tampon that is inserted into a woman's body. Gentle Glide's pledget is comprised of [redacted] REDACTED [redacted]

6. Playtex made [redacted] changes to the construction of the Gentle Glide pledget: [redacted] REDACTED [redacted]

7. The changes referenced in paragraph 6 resulted in a [redacted] REDACTED [redacted] which constitutes New Gentle Glide's new absorbing core. [redacted] REDACTED [redacted] and results in improved fluid displacement (pledget expansion).

8. Playtex conducted *in vitro* testing comparing the Old Gentle Glide pledget to the New Gentle Glide pledget. Playtex received the results of this *in vitro* testing on

April 2, 2007. The test demonstrated New Gentle Glide's improved *in vitro* performance as compared to Old Gentle Glide.

9. Specifically, the *in vitro* testing referred to in paragraph 8 showed that the changes to New Gentle Glide's pledget resulted in (a) [redacted] REDACTED [redacted] and (b) improved fluid displacement, as measured employing gravimetric techniques and a modified version of the standard Sygyna test.

10. The [redacted] REDACTED [redacted] enables New Gentle Glide's pledget to [redacted] This helps provide better leakage protection by compensating for the placement of the pledget in a non-optimal location in the vaginal cavity. Magnetic resonance imaging ("MRI") research demonstrates that non-optimal placement often occurs when women use plastic applicator tampons. The [redacted] REDACTED [redacted] of New Gentle Glide demonstrated by the *in vitro* testing referred to in paragraph 8 helps reduce the potential for leakage caused by such misplacement of the tampon.

11. The modified Syngyna test measures the liquid displacement of a tampon. This constitutes the only approved apparatus employed to measure a tampon's absorbency under regulations promulgated by the Food and Drug Administration ("FDA"). The *in vitro* test referenced in paragraph 8 demonstrated New Gentle Glide's improved fluid displacement because it demonstrated that [redacted] REDACTED [redacted]

12. On March 15, 2007, Playtex submitted a 510(k) to the FDA for New Gentle Glide. The FDA cleared New Gentle Glide on April 13, 2007. Attached as Ex. A

is a true and correct copy of the letter from the FDA clearing the marketing of New Gentle Glide.

13. Playtex introduced the first batches of New Gentle Glide onto the market on May 25, 2007. By the end of 2007, New Gentle Glide was the only version of Gentle Glide being sold in stores.

14. In my experience working with the manufacture of tampons, even minor changes to the basis weight of a fiber pad in the manufacturing process of a pledget could result in an increase in absorbency.

Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing is true and correct, to the best of my knowledge and belief.

Dated: May 30, 2008

Keith Edgett

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Keith Edgett
Vice President
Playtex Products, Inc.
804 Walker Rd.
DOVER DE 19904

APR 13 2007

Re: K070745
Trade/Device Name: Playtex Gentle Glide Plastic and Playtex Gentle Glide Plastic Multipack Tampons
Regulation Number: 21 CFR 884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HIL and HEB
Dated: March 15, 2007
Received: March 19, 2007

Dear Mr. Edgett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure